Exhibit 11

Contains Highly Confidential Materials
Subject to Protective Order

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	Judge Patti B. Saris Chief Magistrate Judge Marianne B. Bowler

DECLARATION OF DANIEL L. MCFADDEN

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I. INTRODUCTION

1. My name is Daniel L. McFadden. I am the E. Morris Cox Professor of Economics at the University of California, Berkeley, and the Director of the Econometrics Laboratory. I am also a principal at *The Brattle Group*. I received a Bachelor of Science degree in physics, with high distinction, in 1957, and a Ph.D. degree in behavioral science, with specialization in economics, in 1962. Both degrees are from the University of Minnesota.

2. I received the 2000 Nobel Memorial Prize in the Economic Sciences for developing methods and theory used in analyzing how consumers and households make choices from sets of discrete alternatives. My work is now a standard tool in analyzing consumer behavior in a wide variety of markets. It is used to determine how people choose one brand of product over others and how they decide to purchase one type of product over another. Discrete choice modeling is used to understand what features consumers value and how they respond to price changes and to product information. My work also is used commonly in making public policy and regulatory decisions.

3. I received the 2000 Nemmers Prize in Economics, awarded by Northwestern University to recognize "work of lasting significance." In 1975, I received the John Bates Clark medal, awarded biennially to the economist under 40 judged to have made the greatest contribution to the profession. I also have received the Frisch medal (1986), awarded biennially for the best empirical paper in Econometrica; and the Outstanding Paper Award of the American Association of Agricultural Economics.

4. I have served as the James Killian Professor of Economics at the Massachusetts Institute of Technology, the Irving Fisher Research Professor at Yale University, and as a Fairchild Distinguished Scholar at the California Institute of Technology. I have been elected a Fellow of the American Academy of Arts and Sciences and of the National Academy of

Science, and have received an honorary LL.D. degree from the University of Chicago, and honorary doctoral degrees from Huazhong University of Science and Technology, the University of London, and the University of Montreal. I have served as President of the Econometric Society and as Chairman of the Berkeley Department of Economics. I served as President of the American Economics Association in 2005.

5. My teaching areas include economic theory, econometrics, and statistics at the graduate level. I have published seven books and more than 100 professional papers. My CV is attached as Appendix A and a listing of materials considered is attached as Appendix B.

6. I have been asked by counsel for the Track 1 Defendants to review and comment upon the declarations issued by Plaintiffs' economic expert, Dr. Raymond Hartman.

7. Dr. Hartman has submitted a declaration regarding his findings of liability and damages in this case dated December 15, 2005 and a supplemental declaration was issued in February 2006. Because these declarations are unclear in certain areas and because materials and data used to create Dr. Hartman's results have not yet been made available through discovery, I cannot complete my analysis at this time. Therefore, I may supplement or modify this report and/or my opinions, and the bases therefore, in light of new information that becomes available though deposition or discovery.

8. I am being compensated for my time in this matter at my standard hourly rate of $850.

II. SUMMARY OF FINDINGS

9. My analysis focuses on the fundamental elements of Dr. Hartman's economic theory and his estimation of damages. Specifically, I consider whether Dr. Hartman's theoretical framework is consistent with basic economic principles, whether the evidence he presents supports his assumed conclusions, and whether the process by which he evaluates his

assumptions is scientific. I understand that other experts address in detail other aspects of Dr. Hartman's report.

10. I find that Dr. Hartman's analysis of causation, liability, and damages is unreliable and incorrect. Dr. Hartman's reports do not support a scientific finding of his central hypothesis that payors shared a common "market expectation" of the spread between AWP and ASP for all NDCs, class members, and time periods, measured by a "yardstick" of 30%. Even if fraud is assumed for purposes of damages, Dr. Hartman's damages analysis overstates the quantum of damages that result. My review shows that Dr. Hartman's assumptions and conclusions contradict basic economic theory and are inconsistent with the evidence he presents. More specifically:

- Dr. Hartman's analysis of liability and damages is not scientific. Dr. Hartman assumes his result and offers no meaningful scientific test of his central hypothesis that expectations about spreads affect reimbursement rates, of the assumptions underlying his yardsticks, or of his empirical results.

- Dr. Hartman's conclusion that plaintiffs would have negotiated lower reimbursement rates with physicians if they had different expectations about spreads is no more than an untested theory.

- Despite indicating that he would undertake surveys of payor expectations, Dr. Hartman offers no direct evidence of what class members expected spreads on Physician Administered Drugs (PADs) to be. Instead he opines that surveys and the direct testimony of the plaintiffs are unreliable evidence of expectations about spreads and their role in setting reimbursement rates.

- Dr. Hartman argues that expectations can be measured from data on contract reimbursements. But Dr. Hartman also finds that contract reimbursement rates have not changed consistent with his theory, suggesting that payors were informed or that expectations about spreads do not determine reimbursement rates. Dr. Hartman, however, concludes therefore that they change only slowly and with substantial lags. If so, Dr. Hartman has no reliable way to test his theory.

- Dr. Hartman assumes that payors did not expect that increased therapeutic or generic competition would increase spreads. There is, however, no evidence that payors expected that spreads for any and all drugs facing therapeutic or generic competition

would be no more than those for drugs that did not face such competition. This conclusion is implausible.

- ▷ Dr. Hartman also shows that it was widely known that competition increased spreads.

- ▷ Those payors who purchase drugs, such as those with mail order or specialty pharmacies or HMOs, and those with the ability to audit or ask their providers of PADs for information, could observe spreads directly.[1]

- ▷ Basic economic theory predicts that spreads for drugs facing competition will exceed those for drugs that do not.

- There is no evidence that if payors' expectations but for the alleged fraud were different, reimbursement rates would be more favorable to payors.

  - ▷ Markets do not generally require buyers to know the sellers' margins to achieve effective competition. For example, consumers probably have inaccurate expectations (or none at all) about the margin on packaged goods they buy at the supermarket, because their behavior is driven by price and not the grocer's margin.

  - ▷ If such information were valuable to payors and was key to the setting of their reimbursement rates, there should be evidence that they sought to obtain accurate data. For example, payors could ask about and/or audit physicians' acquisition costs or commission consultants or surveys to learn more about spreads.

  - ▷ Reimbursement rates realized by TPPs will reflect their relative bargaining power with physicians and the economics of the physician's practice. These characteristics are independent of the payors expectations about spreads.

  - ▷ Dr. Hartman concedes that at least some payors would not change their contracting behavior if they had better information on spreads.

  - ▷ Dr. Hartman's reports indicate that reimbursement rates over time do not appear to have responded as his theory predicts to public information about the actual magnitude of spreads, including up until the present.

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[1] For example, "Aetna has a network of two Oncology Pharmacy Network (OPN) providers to serve members who require products and services related to the treatment of cancer." See http://www.aetna.com/provider/data/onclgy_phm_nwk.pdf.

- If the alleged fraud is based on an incorrect expectation that AWP is a reliable indicator of ASP, as Dr. Hartman's initial theory posed, then the fraud could be cured by correcting payor expectations rather than by changing AWP to conform to the inaccurate expectations. For example, AWP information could be disseminated with a disclaimer that AWP should not be interpreted as a reliable signal of ASP or data on spreads and ASPs could be gathered and disseminated. In this fraud-free, but-for world, all payors would *not* capture the entire value of the allegedly fraudulent spread income that has been paid to physicians for themselves as assumed in Dr. Hartman's damage model. This is because even under Dr. Hartman's assumption that expectations determine reimbursement rates, the ability of a payor to capture the margin earned by physicians will depend on several factors that will differ among payors. These include the relative bargaining power of the payor and the physician, the economics of the physician's practice, and a payor's knowledge of spreads.

    - ▷ Even if payor expectations are informed, the incentives remain to increase spreads as competition increases in Dr. Hartman's model. Dr. Hartman's damages model assumes incorrectly that spreads would drop to less than 30% absent the alleged fraud.

    - ▷ Even if payors are informed that AWP is not a reliable indicator of acquisition cost and even if expectations determine reimbursement rates, payors in different competitive circumstances (or with different knowledge of spreads) will differ in the degree to which they can recover spread income from physicians.

    - ▷ Dr. Hartman's damages calculations therefore are inconsistent with his expectation-based fraud theory and overstate any damages substantially.

- Without information about payors' expectations about spreads, Dr. Hartman makes a series of assumptions about what payors might have believed and about how those beliefs determined reimbursement rates. The result of these assumptions is that his liability and his damages analyses do not depend on what payors expected spreads actually were during the class period for the drugs at issue. Rather, for non-Medicare claims, fraud is assumed by Dr. Hartman's model to exist *per se* whenever drug companies increase spreads for drugs facing competition (primarily by cutting prices) above spreads that exist for drugs not facing competition, regardless of whether payors were aware of the spreads. Described this way, the alleged fraud outside of Medicare must be cured by regulating drug company sticker prices so that spreads cannot exceed 30% (that is, by making them liable for fraud whenever spreads exceed 30 %). However payors are likely to be no better off and may even be worse off when spreads are limited to 30% or less in the actual world.

- If spreads are limited to the level that exists when drugs do not face competition, the incentives to cut selling prices to increase volume of sales to physicians are eliminated. ASPs will be higher in the but-for world than in the actual world where ASPs were cut in order to increase volume.

- Because physicians would still face economic incentives to buy drugs that offered them the highest income under Dr. Hartman's theory, competition would pressure AWPs higher, not lower. That is, a 30% spread on a more expensive drug provides more income to a physician than the same spread on a less expensive drug.

- For Medicare, Dr. Hartman initially offered the opinion that Medicare would have the same expectations as other payors and therefore that liability arose whenever spreads exceeded 30%. Nonetheless, for those drugs whose spread exceeded 30%, Dr. Hartman calculated damages based on a spread of zero. In his supplemental report, Dr. Hartman switches his liability measure so that he finds liability and damages exist *pe se* whenever there is any spread at all on the drugs at issue. Dr. Hartman provides no economic basis for the switch in his Medicare liability measure, no basis for the Medicare yardstick of zero, and no economic theory to support his Medicare damages calculation.

- In his supplemental report, Dr. Hartman also changes his measure of ASP without economic justification to include classes of trade that I understand are not at issue in this case. This raises questions about which spreads Dr. Hartman believes payors believe are relevant to their reimbursement decisions, and how (or why) he believes reimbursement rates to physicians would change, for example, to reflect discounts given in other classes of trade (such as hospitals).

- Dr. Hartman's calculations make arbitrary assumptions that create arbitrary results and are based on small samples of data that reflect considerable uncertainty.

III. BACKGROUND

A. Economic Theory and The Relationship Among Expected Dealer Cost, Dealer Margins, and Sticker Prices

11. From an economic perspective, the central issue in this case involves questions about how sticker prices (AWP) relate to a dealer's cost (AAC), to a dealer's margins (spreads realized by physicians), to prices paid by consumers (reimbursement rates) and to consumer expectations about dealer costs and margins. Before turning to these issues in the context

of physician-administered drugs and Dr. Hartman's conclusions in this case, I discuss these issues in a general context. I do this as background and because the issues posed in this case can arise in many markets and the answers to these fundamental economic questions may apply broadly in many markets.

12. A commonly used example is the new car market, where manufacturers post public MSRPs or sticker prices and provide the goods to retailers at private wholesale prices. For autos, dealer prices are not usually public, and the spreads between dealer prices and MSRPs can vary across models, with manufacturers offering larger dealer discounts ("dealer incentives") for models that face stiff competition and are not selling well.

13. The legal questions in this case can be posed for the example of automobiles: does the failure of manufacturers to disclose dealer prices or to adjust MSRPs so that they closely track dealer prices constitute fraud? Similarly, it must be determined whether damage for fraud has occurred if a customer fails to bargain for a substantial discount off MSRP in circumstances where he could have done better with more accurate data on dealer incentives. If so, is he or she entitled to recovery of the difference between the price he paid and the price he would have paid had he gotten the same markup over dealer cost that was available on models that had no dealer incentives? And if there does exist a legal obligation to make public accurate information on a dealer's cost to the buyer, who should provide it?

14. From an economic perspective, these questions can be informed by consideration of how consumers and dealers respond to economic incentives and to competition, the role of sticker prices and information about dealer costs and margins, and how consumers obtain information important to their buying decision.

15. The first question that is raised by this example is whether, in fact, consumers require information about dealer cost to obtain the best price. It should be clear that competition generally works without consumers requiring such information.

16. When purchasing a good or a service, it is the consumer's retail price that is relevant to the consumer, not the wholesale cost. Of course nearly all retail prices include a markup over the wholesale cost. This is as true for pharmaceuticals as for a carton of eggs. Consumers purchasing a carton of eggs are not harmed because only the retail price is disclosed to them and not the store's wholesale cost of the eggs and the farmer's cost to raise the chickens.

17. The reason that consumers usually do not need to know the wholesale cost is that they seek to find the good or service at the lowest total cost to them rather than to find the lowest wholesale cost to the retailer. Competition occurs as competing sellers lower price to attract volume, and consumers benefit because they respond to signals about the price they will pay, not because they understand more about the wholesale cost to the seller. This is why you might, for example, be aware of the price of a dozen eggs or a bottle of soda at your favorite supermarket but have no understanding or interest in the supermarket's cost for those items. Consumers, nevertheless, get the benefits of price competition at the wholesale level because retailers know these costs and are forced to account for them by retail competition.

18. In some cases, or for some consumers, information about a dealer's cost might be valuable, particularly in situations where they bargain over a price. A second question then arises: what happens if consumers making certain purchases believe they would benefit from information about a supplier's cost? Returning to the car example, a consumer may seek the lowest price and negotiate with alternative dealers to improve their competing offers regardless of dealer cost. However, some consumers may prefer to limit their search and to negotiate more directly with a single dealer, and such consumers may believe that information about cost is useful to them. In this case, what occurs, consistent also with basic economic principles, is that firms develop and monitor cost information and sell that service to consumers. Quite simply, when information is valuable to buyers, they seek it out. In the case of automobiles, various consumer magazines and commercial web sites provide data that purport to assist auto buyers in estimating dealer cost. Note, however, that there is no guarantee that possessing information (accurate expectations) about a dealer's cost will change his offer price at all. This is particularly true when the dealer has a degree

of market power due to limited competing dealerships, for example, or a limited supply of a popular model. Information may be useful in some circumstances, but knowing a dealer's cost does not dictate that you can obtain the car at a particular price or with a price that leaves the dealer a pre-determined margin.

19. A third question is whether consumers would expect that the dealer's cost declines and its profits increase with greater competitive pressures on manufacturers. For example, suppose that gasoline prices increase and manufacturers suddenly find themselves stuck with a large supply of SUVs. Of course, it is well known that increased competitive pressures are likely to lead to lower prices. The manufacturers' incentive to "move market share" is the reason for the reductions in the dealer cost in the first place, and cuts in wholesale prices harm the manufacturer unless it believes that the additional sales justify them. Thus, one would expect that increased competitive pressures on manufacturers will lead to lower wholesale prices, and even consumers who learned nothing about "dealer incentives" would be doubtful that the dealer pressures to "move market share" would be the same for a slow-selling SUV as for a popular fuel-efficient alternative during a period of high gasoline prices. The extent to which such lower wholesale prices will be passed on to consumers will similarly depend on the competitive conditions facing the retail market. The retailer with market power, for example, is more likely to retain the benefits of increased dealer incentives and realize higher margins as a result.

20. To summarize, basic economic theory indicates that: 1) consumers do not necessarily need to know a seller's wholesale cost to find the lowest price; 2) where cost information is valuable, buyers will seek it out, creating incentives for third parties to provide it; 3) prices and margins will reflect competitive conditions, with increased competition for a buyer's business leading to lower prices, all else equal; and 4) if the buyer is a reseller rather than a final consumer, discounts to the reseller may either be retained by the reseller or be passed on to final consumers, depending on the competitive conditions at retail.

21. I note here briefly that requiring public disclosure of wholesale prices is potentially anti-competitive. The well-recognized argument is this: If wholesale prices are not public, then

suppliers can cut prices selectively to gain market share, at least temporarily. This is the normal competitive process, and depending on the competitive conditions among retailers, may lead to lower prices for consumers. However, if wholesale price cuts must be made public, they invite immediate responses from rivals that eliminate the temporary competitive advantage conferred by the price incentive. This in turn removes the incentive to offer the selective cut. This result is counter-intuitive, but is a common phenomenon in the theory of market games, where it is a version of what is called the "chain store paradox." The general economic proposition is that for competition to work, there must be enough private information and opportunities for small extra profits to create effective incentives. As word gets out, other manufacturers observe losses of market share and must cut prices to meet competition. As the process continues competition at retail will force pass throughs to customers, depending on the strength of competition.

22. Finally, if it is determined that customers must be made aware of specific incentives or price cuts provided to a dealer, the dealer is best situated to provide that information to the buyer during the sales process. Note too that if customers do require cost information to get the best price, it is the dealer who has the incentive not to disclose that information, not the manufacturer. The obligation might best be placed on the dealer to disclose its specific incentives and costs for the specific vehicle rather than to require the manufacturer to post a general average wholesale price over a broad group of dealers and with a lag.

B. Pricing and Competition in the Health Care Market

23. The Court's expert, Professor Berndt, and Dr. Hartman, each note that the market for physician-administered drugs has some features that may lead to economically inefficient outcomes or to "abuse and mischief."[2] Among these features is the insertion of a third party payor (TPP) between the consumer and the physician, the relatively unique circumstances of each drug purchase decision, the highly specialized knowledge of the physician, and the

[2] Report of Independent Expert Professor Ernst R. Berndt to Judge Patti B. Saris, February 9, 2005 at pp.41-42.

small size of the physician-administered drug market relative to other health care markets.[3] I review briefly the basic features of the markets at issue in this case and note at the outset that my analysis focuses not on the very broad question of inefficiencies in health care markets, which undoubtedly exist for myriad reasons. I focus instead on the role of AWP, ASP, reimbursement rates, and consumer expectations about these prices in determining the prices consumers and insurers pay for services and drugs provided by physicians. The relevant economic question in this case is not what a perfectly competitive health care market would look like, but what a market absent the alleged fraud would look like given the healthcare marketplace as it existed during the class period.

24. The products in question for the certified classes are drugs sold by defendant pharmaceutical companies and covered by Medicare Part B. These are generally sold to individual physicians or physician practices and are generally referred to as "physician administered drugs" (for this report, "drugs" or "PADs"). They also include the self-administered drugs covered by the durable medical equipment coverage of Medicare Part B, such as Albuterol. The price in this transaction is the "average selling price," or ASP, and will depend on the incentives and competitive conditions that face physicians when they make decisions to purchase drugs from manufacturers.

25. Physicians are often reimbursed for these drugs by either plaintiff health care plans or insurers (third party payors, or TPPs) or individual plaintiff patients (for example individual plan beneficiaries or Medicare patients who co-pay a share of the drug costs). Payors at issue in this case have negotiated some contracts that pay physicians based on a published sticker price for each drug, the "average wholesale price" or AWP.[4] Contracts specify a range of terms that provide for reimbursement at a discount or premium to AWP. The transactions between payors and physicians reflect the incentives and the competitive

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[3] See, for example, Berndt Report at pp. 41- 45 & pp. 52-53.

[4] I understand that many payors in this case also have negotiated contracts with physicians that do not reference AWP in the reimbursement provisions for PADs.

conditions that face physicians when they decide whether to join a payor's insurance network.

26. In analyzing the effects of competition on consumers, payors, and physicians, it is important to keep in mind that there are different competitive conditions and incentives that face each of the parties at each stage of the market. The first stage is a "wholesale" market in which pharmaceutical companies sell drugs to physicians (or to the physicians' suppliers) at the net average sales price or ASP.[5] The second stage is a "retail" market in which physicians sell drugs to patients and third-party payors at prices that may be marked up or down from the AWP.

27. The "spread" between the reimbursement rate and the physicians's acquisition cost is income to the physicians.[6] For example, because there is a markup on drugs, physicians face financial incentives to choose therapies based on higher spreads, all else equal. But note that this is a function of the way the relationship between the payor and the physician is organized and the incentives exist at every level of AWP.

28. The revenue to pharmaceutical companies is the ASP times the quantity sold. Pharmaceutical companies are concerned with tradeoffs between the selling price they can obtain from physicians, the volume of sales, and the willingness of insurers to cover their drugs. Pharmaceutical companies can compete against companies offering therapeutic or generic alternatives by lowering their ASP to gain market share for their products. Competitive pressure on physicians arises from the ability of insurance networks to exclude

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[5] Physicians may obtain PADs directly from pharmaceutical companies, from specialty pharmacies, or from suppliers often referred to as wholesalers. For simplicity, here I use the term wholesaler to refer to a physician obtaining PADs directly from a pharmaceutical company.

[6] Note that if the physician acquires the PADs from a wholesaler rather than a manufacturer, the physician's average acquisition cost (or AAC) differs from the average selling price received by the manufacturer by the amount of the wholesaler's margin on the drug. For simplicity, I use the terms average selling price and ASP to refer also to the physician's acquisition cost, but in cases where physicians acquire PADs from sources other than directly from a manufacturer, the spread to a physician should be measured by a comparison of the reimbursement rate to the physician's acquisition cost.

a physician from their coverage and from the prices consumers face for the unreimbursed portion of drugs and services.

29. The cost of a PAD to the TPP and the patient will reflect the agreed-upon reimbursement rate between a payor and a physician and the co-pay arrangement between the TPP and the patient. The TPPs adjust their reimbursement rates in the retail market to attract physicians to their networks and provide services that attract patients.[7] The use of AWP in the retail market as a basis for reimbursements will have no effect on the final retail price if that market is competitive.

30. Similarly, when drugs have therapeutic or generic competition, ASP will be determined by competition to sell to physicians. If physicians in the retail market have market power, improvements in their revenue as a result of declines in ASP caused by increased wholesale competition may not be passed on to TPPs and patients through competition among physicians.

31. In examining the role of AWP, the substantive questions are 1) why in repeated bargaining with multiple physicians in successive periods, TPPs do not acquire direct information on the lowest reimbursement rate that physicians will accept, 2) why if knowledge of drug acquisition cost is valuable to bargaining, the TPPs do not ask physicians to provide it or seek to buy or otherwise acquire this information, 3) what is the legal responsibility of pharmaceutical companies to provide AWP prices that stand within a limited spread from ASP, and 4) how pharmaceutical companies would compete for business if they were legally required to cap the spreads that influence physician interest in their products.

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[7] "Survey of Health Plants Concerning Physician Fees and Payment Methodology," Dyckman & Associates, August 2003, p. 18.

C. Overview of Dr. Hartman's Analysis and Conclusions

32. Dr. Hartman's analysis begins with an assertion regarding some of the drugs at issue in this matter: As therapeutic or generic competition for a drug arises or increases, pharmaceutical companies increase the margin between the price at which they sell drugs to physicians and the list price of those drugs. This is accomplished largely, but not exclusively,[8] by dropping the selling price of the drug to physicians without decreasing the sticker price for those drugs. The spread allegedly is increased to create incentives for physicians to purchase their drugs rather than those of competitors:

> Dr. Hartman:
> [Payors] have expected that AWP is larger than ASP by a *reasonably predictable* amount.[9]
>
> ***
>
> . . . the alleged AWP scheme was effectuated when a manufacturer increased the AWP of the drug and/or decreased its ASP in order to offer financial incentives to providers to move market share.[10]
>
> ***
>
> Second, assuming the allegations are true, Defendant Drug Manufacturers offered discounts, rebates and/or other price offsets to specifically targeted entities (providers, PBMs and retailers) that had the ability to "move market share."[11]

33. As he presents it, Dr. Hartman's description of the alleged fraud rests on the critical assumptions that the spreads reached levels not expected by the payors and that payors would have adjusted their reimbursement rates to reflect their expectations of spreads.

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[8] Increases in AWP are observable to payors through claims data, as is the emergence of competitive alternatives.

[9] Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification, September 3, 2004, p. 7. Emphasis in original.

[10] Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages, December 15, 2005, p. 38.

[11] Hartman Declaration, September 4, 2004, Executive Summary, p. 1.

Dr. Hartman:

> [T]he alleged fraud caused injury to the extent that the Spread and the AWP diverged from the but-for world *in ways unexpected by and unknown to the Class*;"[12]
>
> ***
>
> The spread must be increased secretly, because if such spreads were understood to exist, competitors would behave to eliminate them.[13]
>
> ***
>
> The negotiation also relies upon an anticipation that the AWP provides a signal for the underlying spreads. Had the existence of the "mega-spreads" been perceived and understood by TPPs, those payers [sic] would have negotiated more aggressively than they did, leading to lower reimbursement rates.[14]

34. Dr. Hartman assumes that the level expected by all payors for all National Drug Codes (NDCs) and time periods was no more than the spread that existed on single-source innovator drugs, about 30%. He refers to this level as his "yardstick":

Dr. Hartman:

> In the absence of therapeutic competition, a given manufacturer would find it unnecessary and unprofitable to increase spreads to move market share; [footnote omitted] if uniquely efficacious, the clinical profile of the drug would be sufficient to move market sales. Hence, successful 'break-through' innovator drugs serve as reasonable yardsticks for 'but-for' spreads...[15]
>
> ***
>
> If the actual spread exceeds the but-for spread, I can conclude that the AWP scheme led to reimbursement in excess of those reasonably expected by the market.[16]
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> ***

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[12] Deposition of Raymond S. Hartman, October 8, 2004, p. 12. Emphasis added.

[13] Hartman Declaration, September 3, 2004, p. 15, Attachment C. Emphasis in original.

[14] Hartman Declaration, December 15, 2005, pp. 9-10.

[15] Hartman Declaration, December 15, 2005, pp. 15-16.

[16] Hartman Declaration, September 3, 2004, p. 18.

> Specifically, if a manufacturer either raises its AWP and/or lowers its ASP such that the realized spread exceeds 30% for a given NDC for a given period of time (I choose a year), I conclude that the manufacturer has fraudulently increased the spread on that NDC in that period to move market share.[17]

The Court summarized the argument as follows:

> Plaintiffs rely on the Hartman yardstick methodology as a method of calculating aggregate class damages. They assert that they can prove through the economic theory of revealed preferences, through the comparison method, and through surveys that *TPPs expected the spread between AWP and AAC or ASP to be no more than 33% for brand-name drugs.* Plaintiffs assert that with these methods they prove that the fraud was the proximate cause of injury (inflated price) even for those with bargaining power and sophistication.[18]

35. Dr. Hartman estimates damages to these payors on the assumption that absent the alleged fraud, competition would cause pharmaceutical manufacturers to set the AWP of each drug to reflect a spread of no more than 30% above the average prices at which they actually sold each drug to physicians in the as-is world (that is, in the presence of the alleged fraud). Dr. Hartman argues that "[payors] expected and believed the spread to be less than 30 percent."[19]

36. For Dr. Hartman's liability analysis to be proven correct, therefore, several theoretical and empirical assumptions must be proven correct:

Hartman must prove:

- That if an AWP is set for a drug that reflects a markup over the physician's cost greater than the amount payors expect such a markup to be, the manufacturer has committed fraud;

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[17] Hartman Declaration, December 15, 2005, p. 40.

[18] Memorandum and Order Re: Class Certification, August 16, 2005, p. 83. Emphasis added.

[19] Hartman Deposition at 791:15-16.

- That class members expected that the relationship between AWP and ASP for all drugs was governed by a "reasonably predictable amount" which is empirically estimable;

- That the "reasonably predictable" spread for any and all drugs facing therapeutic or generic competition was equal to the spread that payors expected for single-source innovator drugs not facing such competition. That is, payors would have to expect that as new competition entered the market, manufacturers did not cut selling prices to physicians; and

- That the reasonably predictable spread in no case exceeds 30%.

37. For Dr. Hartman's damages conclusions to be correct requires that payors set reimbursement rates based on their expectations about spreads, and that changes in payors' expectations would permit them to change reimbursement rates to capture dollar-for-dollar the value of the changes in expected spreads.

38. Dr. Hartman bases his damage model either on these assumptions or on an alternative definition of fraud that assumes that increasing spreads "to move market share" is *per se* fraudulent. His damages calculations assume that in the absence of fraud, drug companies would have cut their selling prices to the same extent that they did in the presence of the alleged fraud, but they would have reduced list prices correspondingly to preserve the spread at the level that exists for drugs not facing competition.

39. For Medicare claims, Dr. Hartman's damages analysis incorporates his (legal) conclusion that Medicare statutes required physicians to be compensated at their actual acquisition cost when liability is found. Dr. Hartman's analysis assumes liability under two alternative standards: 1) whenever spreads exceed 30%; or 2) for all subject drugs over the entire class period *regardless of the level of the spread between AWP and ASP*.

40. Based on these assumptions, Dr. Hartman argues in effect that consumers and insurers lose because of the failure of some insurers to bargain away added profits of physicians induced by competition among pharmaceutical companies. This argument requires that insurers are unaware that AWPs do not track ASPs, are either unaware of the emergence of competition

or are unaware that the introduction of competition among products generally leads to lower prices, and have no information channels or mechanisms to obtain ASPs. Therefore, under those circumstances, the failure of insurers to look after their own interests is explained entirely by the fact that drug companies do not make ASPs public or ensure that published AWPs track ASPs by a "reasonably predictable amount."

41. These assumptions and conclusions can be tested both through standard principles of economic theory and empirically. If any of these assumptions is incorrect, Dr. Hartman's conclusions also will be incorrect.

IV. DR. HARTMAN'S ANALYSIS DOES NOT MEET A SCIENTIFIC STANDARD

42. In the sections that follow, I show that Dr. Hartman's analysis and conclusions regarding liability and damages are implausible. Here, I examine the approach followed by Dr. Hartman to test the critical hypotheses and assumptions that underlie his conclusions and to contrast his approach with standard scientific methods. I show that despite claims of performing science, Dr. Hartman repeatedly follows an incorrect scientific approach.[20]

43. The economics profession, to the extent it is applying scientific methods to a problem, generally proceeds in four basic steps:

i. Specifying a clear model or hypothesis to be evaluated or tested, including identification of critical assumptions;

ii. Collecting reliable data and information;

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[20] Dr. Hartman testified: "Yeah, fair is – I'm not being asked to be fair here, I'm being asked to be – to do science . I'm going to ask that to the extent that it's scientifically sensible and can be ascertained via a survey about how their expectations were informed relative to the data that I see in the industry." Hartman Deposition, October 8, 2004, p. 229.

iii. Analyzing the model or hypothesis using data, including calibrating the model, estimating unknown parameters, and testing of hypotheses; and

iv. Reaching reliable conclusions, forecasts, findings, predictions, and inferences based on the previous steps.

44. Dr. Hartman's analysis in effect assumes his conclusion about the existence of the alleged fraud. This is most easily seen by working backwards in a series of steps from the damage calculation:

i. Dr. Hartman argues that actual spreads in excess of the but-for yardstick of 30% constitute evidence of liability for fraud and damages;[21]

ii. Dr. Hartman argues that plaintiffs held "market expectations" that the relationship between AWP and ASP was "a reasonably predictable" amount;[22]

iii. Dr. Hartman argues that the "reasonably predictable amount" can be estimated by assuming that class members accurately held "market expectations" that a common "yardstick" of 30% applies as a conservative upper limit to expected spreads for all NDCs and time periods in the but-for world;[23]

iv. Dr. Hartman argues that all NDCs, class members, and time periods are expected to share a common expected "yardstick" in the but-for world because "lack of pricing transparency" (*i.e.*, little or no data) on either actual or expected spreads means there is no reason to assume otherwise;[24] and

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[21] Hartman Declaration, December 15, 2005, p. 40.

[22] Hartman Declaration, September 3, 2004, p. 7.

[23] Hartman Declaration, December 15, 2005, p. 40.

[24] Hartman Declaration, December 15, 2005, p. 42.

v. Dr. Hartman argues that four sources of information (later reduced to three) can be reliably used to infer that plaintiffs' "market expectations" are based on a "yardstick" threshold of 30%.[25]

45. If the theory or empirical support for any of these steps is unreliable, the damage calculation will be unreliable because each step in the chain of argument is needed to reach the conclusion.

46. Dr. Hartman's damage methodology misapplies basic principles of hypothesis testing in economics. Science requires providing convincing evidence that a critical hypothesis should be accepted. The appropriate test is whether alternative explanations can be rejected as unlikely or impossible because they conflict with compelling evidence. Dr. Hartman does not undertake such an approach and often accepts his hypothesis without consideration of alternatives that explain his data or based on an inability to find appropriate data with which to test it.

47. In the absence of compelling data, Dr. Hartman's approach can be used to confirm many conflicting hypotheses, however implausible. Using this approach, weak or nonexistent data will mean that either a hypothesis or its antithesis will be accepted depending on which is arbitrarily accepted as the candidate hypothesis. To prevent this, the economically correct approach is as follows:

- Pose a candidate hypothesis that something is true; and then
- Accept the candidate hypothesis with confidence only if strong evidence rules out (*i.e.*, rejects) the antithetical or contrary hypothesis with confidence.

48. The Hartman approach tips the scales in favor of accepting his central hypothesis of a common yardstick for all class members, NDCs and time periods for the but-for world in the absence of convincing data, because it accepts the hypothesis unless it can be convincingly disproved. To the extent that Dr. Hartman's evidence is inconclusive or irrelevant, however,

[25] Hartman Declaration, December 15, 2005, pp. 14-17.

it should have caused him to reject the hypothesis of a common yardstick as implausible. Moreover, to the extent that the evidence in the Hartman Report is relevant, it actually supports rejecting the hypothesis and accepting the alternative that there is no common yardstick that can be calculated reliably. Dr. Hartman's analysis therefore is fundamentally flawed. Dr. Hartman makes the same basic error in hypothesis testing when evaluating the data sources he uses to establish his 30% estimate of the yardstick. I comment briefly on the methodology used by Dr. Hartman to test each of the critical assumptions of his methodology.

49. **Dr. Hartman's Assumption: Any evidence of actual spreads in excess of the but-for yardstick of 30% can only be explained by fraud.**

Dr. Hartman makes no investigation of whether this assumption is theoretically or empirically true. I explain in this report why competition is a critical factor that did and would be expected to explain spreads in excess of 30%. Dr. Hartman also fails to test this assumption against direct evidence that payors either knew of spreads in excess of the 30% yardstick or "simply did not care," thereby contradicting his expectations theory of liability. Nor did he analyze how changes in expectations about spreads would be expected to change reimbursement rates or examine evidence that reimbursement rates already reflect knowledge of spreads during the damage period.

50. **Dr. Hartman's Assumption: Class members believed that there was a spread between AWP and ASP and they expected that the relationship between AWP and ASP was governed by a "reasonably predictable amount" which is empirically estimable.**

The appropriate scientific test would be to develop data on the expectations of class members to determine if the alternative hypothesis – that no such expectation existed – could be ruled out. Dr. Hartman indicated in the earlier phases of this proceeding that he would

survey expectations.[26] No such test was conducted and no data regarding whether class members generally had expectations about the level of spreads, and if so what they were, were introduced. As I have discussed above, there exists evidence that many payors did not have this expectation and that several public surveys which Dr. Hartman suggested reflect and inform expectations show clearly that spreads increase as competition increases.

51. **Dr. Hartman's Assumption: The same 30% yardstick applies to all class members.**

Dr. Hartman assumes that the same 30% yardstick applies to all class members, because he believes that there are no data to justify otherwise: "There is no reason to assume that 'each TPP had a different level of knowledge regarding the spread ...."[27] This is another example of Dr. Hartman's accepting a hypothesis because he believes there are no data to refute it. However, on numerous occasions, he states that there were in fact differences in payor knowledge of spreads.[28]

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[26] For Example, Hartman Deposition at 223: 8-18 and at 229: 5-19.

[27] Hartman Declaration, December 15, 2005, p. 9.

[28] Hartman Deposition at 687:19-20: "Well expectations in the market vary. I mean there is a distribution of expectations. At 724:3-6, Dr. Hartman characterizes those who "don't care what acquisition cost is" as follows: these are people, you know, wailing in the wilderness.

52. **Dr. Hartman's Assumption: Class members believed that the maximum spread of 30% would not be exceeded by any NDC covered in any calendar year.**

This assumption implies that class members believed that the ratio of AWP to ASP was at all times less than 1.3 for every NDC over a period of one calendar year. Dr. Hartman does not conduct any tests to validate the view that payors formed expectations at the NDC level and that these expectations were updated each calendar year. He simply assumes that, for example, if a drug had average spreads less than 30% over a two-year average but exceeded 30% in one year, this would violate payor expectations. This is especially curious because Dr. Hartman argues that information disseminates slowly and implies that payor expectations formed more than a decade ago persist today even in the face of new public information.[29]

53. **Dr. Hartman's Assumption: Class members expected that the maximum spread of 30% did not change over time.**

Dr. Hartman finds evidence of increasing awareness by the class members that spreads were increasing over time.[30] However, damages are based on the same 30% yardstick in every period. The justification is not that class members did not change their expectations because they were unaware of the increased spreads over time, but that they did not act on the new information.[31] As I explain below, if lags explain the inability of his expectations model to predict reimbursement rates, then reimbursement rates will not be accurate indicators of expectations (as Dr. Hartman assumes). Moreover, if TPPs' reimbursement rates do not reflect current expectations and do not change in the period studied by Dr. Hartman, Dr. Hartman lacks objective evidence to prove his theory of expectations and revealed

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[29] See for example Hartman Declaration, December 15, 2005, p. 20 and p. 42 and Hartman Deposition, October 8, 2004 at pp. 202-203. It seems implausible to assume, as Dr. Hartman does, that if they had the data, class members would test annually at the detailed NDC level to see whether their expectations had been violated, yet wait years before taking any action on any new information.

[30] Hartman Deposition at 732:10-733:8.

[31] Hartman Deposition at 765:15-766:9.

preferences, because revised expectations about spreads in response to new evidence have yet to be revealed.[32]

54. **Dr. Hartman's Assumption: In the absence of a direct measure of class members' expectations, three surrogate sources can be reliably used to infer that the "reasonably predictable" spread is not more than 30% for any single-source PAD not facing therapeutic competition.**

Dr. Hartman relies here on three comparator drugs,[33] OIG and ASCO surveys, and contracts between physicians and payors to support his assumption that expectations for spreads could not exceed 30%. None of the data sources reveals expectations. There is no evidence offered that the payors formed their expectations based on these data, some of which are not public. The data sources that were public show clearly that some drugs had spreads well in excess of 30% and that spreads increased with competition.

Dr. Hartman also ignores or failed to identify other public studies that also should have led him to reject his hypothesis. For example, one of the products at issue in this case -- Albuterol -- is the subject of six OIG reports, all of them showing spreads far in excess of 30%.[34]

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[32] Dr. Hartman states at 851:5-8, 20-22: "I am seeing it is the same – they are revealing the same kind of contractual reimbursement rates that were reflective of 10 years before that ... all I am saying is that I don't see – and here *they have decided not to do it* [revise reimbursement rates]. *Now maybe no one will decide to do it.*" Emphasis added.

[33] In Table 3 of his Declaration of December 15, 2005, Dr. Hartman provides a list of "drugs of interest." At p. 39, however, he indicates that he analyzed data on spreads for only Zofran, Taxol, and Blenoxane.

[34] See Office of Inspector General Reports: *"Excessive Medicare Reimbursement for Albuterol,"* March 2002, OEI-03-01-00410, *"A Comparison of Albuterol Sulfate Prices,"* June 1996, OEI-03-94-00392, *"Update: Excessive Medicare Reimbursement for Albuterol,"* January 2004, OEI-03-03-00510, *"Suppliers' Acquisition Costs for Albuterol Sulfate,"* June 1996, OEI-03-94-00393, *"Are Medicare Allowances for Albuterol Sulfate Reasonable?,"* August 1998, OEI-03-97-00292, and *"Medicare Reimbursement of Albuterol,"* June 2000, OEI-03-00-00311.

55. In the remainder of this report, I show that when Dr. Hartman's assumptions and conclusions are evaluated in light of basic economic theory and in light of undisputed economic incentives faced by physicians, payors, consumers and drug companies, it becomes clear that they are economically implausible.

V. DR. HARTMAN'S LIABILITY ANALYSIS: WAS THERE A MARKET EXPECTATION OF SPREADS AND IF SO WAS IT THAT THE SPREAD ON ANY NDC WOULD NEVER EXCEED 30%?

A. Lack of Direct Evidence on Payor Expectations

56. As a threshold matter, and assuming for the purpose of argument Dr. Hartman's theory of liability, *the correct question is not what was the spread for drugs not facing therapeutic or generic competition.* Rather, the correct question is*: what did payors actually expect spreads to be for those drugs that did face competition - and in particular for the drugs at issue in this case?* The Court appears also to have anticipated that this was what Dr. Hartman would provide, as he acknowledges in his report:

> [Judge Saris] concludes, 'Hartman terms his overall approach the 'yardstick method' because he intends to determine *what the market reasonably expected the spread to be on average* (*e.g.*, AWP is 25% above the average sales price, ASP), and compare this number to the actual spread (*e.g.*, AWP is 100% above ASP) to calculate aggregate Class-wide damages.'[35]

57. Although Dr. Hartman repeatedly testified about how he could develop direct evidence on the expectations of class members, he failed to do so:

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[35] Hartman Declaration, December 15, 2005, p. 14. Emphasis added.

> Dr. Hartman:
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> ...I'm going to design representative surveys or samples of entities that represent certain parts of the spectrum within the class, within PBMs, within retailers, within mass merchandisers, and perhaps for the manufacturers. I'm going to get claims data that reveals what actually happened, and I'm going to ask that to the extent that it's scientifically sensible and can be ascertained via a survey about *how their expectations were informed relative to the data that I see in the industry*.[36]
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> ***
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> [L]et's be very clear about class members. What we're going to need is a -- to identify using standard statistical methods a number of selected types of third-party payers and also PBMs and also retailers differentiated in various ways. And we're going to get claims data and *data as to expectation and knowledge for those representative entities* to characterize the class as a whole and the transactions as a whole.[37]
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> ***
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> [O]bviously during the damage phase of this, I'm going to have to talk to a lot of Blue Cross Blue Shield administrators and people at Cigna and Aetna and a variety of places.[38]

58. Dr. Hartman's damages and liability report introduces no surveys nor directly cites any deposition evidence[39] showing what were the expectations of the class members. Instead of

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[36] Hartman Deposition at 229:5-19. Emphasis added.

[37] Hartman Deposition at 223:8-18. Emphasis added.

[38] Hartman Deposition at 92:15-20.

[39] At his deposition, 708:16-709:18, Dr. Hartman indicated that he did not explicitly cite any payor deposition in his materials relied upon, but intended to indirectly reference such sources when rebutting Mr. Young's report in his Attachment K of the damage report. See also Hartman Deposition, 705:6-706:6. However, when asked about testimony evidence from payor depositions that appeared to contradict his theory, he argued that the deponents were not suitably experienced or qualified. (See, for example, Hartman Deposition, 749:8-10, 752:18-753:5, 755:1-3, 11-14, where he says: "this ... has no evidentiary value that I see ... this deponent has little credibility as an understanding of what expectations were, relations were, period." At deposition 791:17-21, Dr. Hartman states that even if payors said that they expected spreads greater than 30%, that would not disprove his hypothesis that they did not.)

collecting information "directly from the horse's mouth," as he had planned,[40] Dr. Hartman argues now that class members' self-reported expectations are not reliable.[41,42,43] Thus, Dr. Hartman appears to be claiming that he is more knowledgeable about the expectations of payors than the class members themselves. It also is curious that Dr. Hartman has not presented any data on payors' actual market expectations about spreads, yet he claims that: 1) he can develop reliable estimates of the beliefs of the plaintiffs about spreads and 2) that these beliefs would fall into a small range whose upper limit can be determined and 3) these beliefs applied to every class member, every NDC, and every time period.

59. Instead of showing what plaintiffs' expectations were, Dr. Hartman supports his assumptions using data from three surrogate sources, none of which contains data on the expectations of the class. He uses these sources to estimate what actual spreads have been for single-source innovator drugs not facing competition, leaving untested the propositions that those spreads were understood by class members and that no class member expected that the spread on any drug facing competition exceeded such spreads.[44] A review of each of the data sources, however, shows that if payors relied on this information or that it reveals their expectations, they would in fact expect that spreads on drugs facing therapeutic or generic

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[40] Hartman Deposition at 702:11-705:3.

[41] Hartman Deposition 694:6-7, 702:2-5.

[42] Dr. Hartman argues that the direct testimony of the class members regarding their expectations and about whether they rely on acquisition costs to set reimbursement rates is unreliable. Nevertheless, he appears to rely on information that individuals at payors were "flabbergasted" when they allegedly came to understand the level of spreads in reaching his opinions on liability. See Hartman Deposition at 959:9-960:10.

[43] At deposition transcript 1241:22-1242:12, Dr. Hartman stated that the Cigna representative, who he had previously proposed to rely upon, did not seem to have "a lot of experience in the health care area" and "might be someone who studied it less, is less familiar with the nuances." Similarly, Dr. Rosenthal agrees at numerous places in her deposition: she states that self-reported expectations of payors are unreliable. (See Rosenthal Deposition 138:13-15, 139:2-3, 139:11-15, 141:13-15, 155:12-14, 155:22-156:3.) However, she seems content to rely on her interpretation of documents produced by defendants in discovery: "They corroborate my economic analysis. They look at strategic incentives from the words of the defendants themselves." (Rosenthal Deposition 355:20-22.)

[44] I note that those payors who purchase drugs, such as those with mail order or specialty pharmacies, or with the ability to audit providers could observe spreads directly.

competition would be higher than the spreads on single-source innovator drugs, contrary to his central hypothesis.

B. Comparator Drugs

60. Dr. Hartman's first source of information is data on comparator drugs in periods when they were unaffected by the alleged fraud. He cites NDCs for three such drugs, Zofran, Taxol and Blenoxane[45] and shows that the annual[46] average spreads on these drugs fall within an 18%-27% range during the years in which they did not face any therapeutic or generic competition.[47]

61. Again, there is no evidence offered that the payors formed their expectations based on these three drugs, and the information he examines was confidential and not available to parties outside this litigation.

62. Nonetheless, Dr. Hartman's data for the three drugs shows spreads for both competitive and non-competitive periods. The spreads on the three drugs were significantly higher during periods in which they faced therapeutic or generic competition, as Dr. Hartman acknowledged:

> Dr. Hartman:
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> The data shows that once Kytril became an active competitor, Glaxo increased their AWP while at the same time decreasing their ASP. This increased their spread and allowed them to effectively market

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[45] Dr. Hartman selectively uses NDCs or averages over NDCs. For example, for Zofran and Blenoxane he chooses a specific NDC, while for Taxol he uses an un-weighted average across all NDC.

[46] The choice of an annual estimation period is arbitrary. ("I choose a year" Hartman Declaration, December 15, 2005, p. 40.) I note that Dr. Hartman does not explain why or how payors updated their expectations on a calendar-year basis. In his initial report, for example, he had indicated that a quarterly analysis could be appropriate. See Hartman Declaration, September 3, 2004.

[47] Hartman Declaration, December 15, 2005, p. 39.

> Zofran to physicians based on the spread which was much higher than their 20% spread prior to Kytril's entry.[48]
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> ***
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> The data shows that at the time of the first generic, the BMS spread for Blexnoxane increased substantially.[49]

63. Thus, to the extent that actual spreads for these drugs were transparent to payors and informed payor expectations, they indicate payors would have expected higher spreads during periods of competition, and these data refute his central hypothesis regarding expectations. However, if these spreads were not transparent to payors, they could not have informed those expectations or serve as an indicator of what expectations were.

C. Publicly Available Sources

64. A second source of information relied on by Dr. Hartman is publicly available reports that gave information from physician surveys about spreads. Dr. Hartman considers two such reports, the 1992 report of New York State Inspector General (the "OIG survey") and a 2001 report published by the American Society of Clinical Oncologists (ASCO) on Medicare payment reform (the "ASCO report"). As with the comparator drugs, Dr. Hartman offers no evidence that payors relied on these two studies to form their opinions on expected spreads, though he does claim that such documents reflect and inform payor expectations.[50]

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[48] Hartman Declaration, December 15, 2005, Attachment F, p. 4.

[49] Hartman Declaration, December 15, 2005, Attachment F, p. 9.

[50] Dr. Hartman states: "It is reasonable to expect that the findings of these reports form some part of the basis for beliefs about the typical "spread" between AWP and actual acquisition costs of providers (physicians) and retail drug stores." (Hartman Declaration September 3, 2004, Attachment D, p. 9); and "These reports provide preliminary measures of reasonable industry expectations concerning the spread between AWP and ASP for brand-name orals, generic orals and physician administered drugs." (Hartman Declaration September 3, 2004, Attachment D, p. 9) He states also that: "As cited in 22. b) above, in the course of my analysis for this matter I have reviewed a variety of publicly-available survey research *summarizing the "market" expectations of spreads for single-source physician-administered drugs.* (Hartman Declaration December 15, 2005, p. 39.)

1. The OIG Report

65. The OIG survey was limited in scope. It covered thirteen chemotherapy drugs, five New York State physicians, two Medicare carriers and a limited time period (January to July 1991). Spreads were averaged by drug, not by NDC. The OIG study warned:

> This review represents a limited analysis of physicians' costs for 13 chemotherapy drugs. The conclusions reached may not apply in all cases.[51]

66. If the OIG study in fact does reveal payor expectations, then it supports a finding that payors in fact expected spreads for drugs facing therapeutic or generic competition to exceed those for single-source innovator drugs. For example, the 1992 OIG study explicitly states that there is no consistent relationship between AWP and ASP:

> Since the Red Book [the source of AWP used by the two New York State Medicare carriers] does not represent its AWP as a measure of the physician's acquisition cost for drugs, we compared physicians' invoice costs to Red Book's AWP. We found that such costs were not only generally significantly less than AWP, but that there can be a wide variety of AWPs for a given drug depending on the manufacturers and the form of the drug (*e.g.*, solution, powder, lyophilized powder). . . Considering that we also found that there is no single discount rate which can be applied to the AWP to provide a reasonable consistent estimate of the physician's acquisition cost, we do not feel that AWP provides a useful measure of the acquisition cost for a drug to physicians.[52]
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> We also found that the relationship between AWP and cost for multiple source drugs varies, depending on large part on the manufacturer" (OIG, p. 5) and that "[O]ne brand name manufacturer

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[51] "Physicians' Costs For Chemotherapy Drugs", OIG Study, Appendix II, 1992, p. 11.

[52] "Physicians' Costs For Chemotherapy Drugs," OIG Study, Appendix II, 1992. Emphasis added.

> sells this drug (Cyclophosphamide, 500 mg] at 20 percent below AWP while another sells it at 59 percent below AWP.[53]

67. In fact, the OIG study presents much larger spreads. Appendix III of the OIG study shows that invoice costs for PADs (expressed as a percentage below the AWP) differed greatly among drugs. Sales from brand name manufacturers varied from 20% off of AWP to 83% off, while sales from oncology wholesalers varied from 12 to 17% off AWP for one drug to 81 to 82% off AWP for another. An invoice cost of 80% below AWP indicates a spread of 400%. Moreover, the 400% spread comes from a limited sample of drugs; if one found such a spread in a small sample, it would be expected as a statistical matter that in the entire population of drugs there are some with spreads significantly larger than 400%. That is, since the study provides only a sample of spreads, it would be expected that for all drugs, the highest spreads exceed the highest spread observed in the sample.[54]

2. The ASCO Study

68. The ASCO study cited by Dr. Hartman was a critique of the Medicare payment methods and did not include any new survey of spreads. Nevertheless, had it been relied upon to form expectations on spreads during the damage period or if the survey reveals expectations of the payors, it would refute the key hypothesis of the Hartman Declaration, that class members expected the same spreads on all drugs and time periods.

> Although WAC represents the price at which manufacturers typically sell to wholesalers, *neither WAC nor AWP is necessarily a reliable guide to the price paid by the end user.*[55]
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[53] "Physicians' Costs For Chemotherapy Drugs," OIG Study, Appendix II, 1992. p. 7.

[54] This general statistical principle was recognized by Dr. Berndt when he noted that "[t]he 'high touch, high cost' characteristic of the physician-administered drugs also implies that the statistical variance from any sample of information could be very high, further jeopardizing the reliability of any single information source." (Berndt Report at p. 53.)

[55] Reform of the Medicare Payment Methods for Cancer Chemotherapy, ASCO, May 2001. Emphasis added.

> ... payment amounts for drugs under state Medicaid programs and *private insurance plans assume that the AWPs are inaccurate ....*[56]

69. The studies clearly show that such competition increases spreads, and it is not appropriate to refer to them only to determine the spreads on drugs that do not face competition. As Dr. Hartman testified:

> Dr. Hartman:
> [A]nyone attempting to understand the results of a survey wants to look at...the results and look at the details. You will look at – you will look at all aspects of it that you can in order to be as informed as you can."[57]

3. Other Public Studies

70. Other public studies conducted by the OIG but not cited by Dr. Hartman also show that PADs had spreads in excess of 30% and that AWP was not a reliable indicator of acquisition costs.[58]

D. Contractual Reimbursement Rates

71. As his third source, Dr. Hartman argues that the range of payor expectations about the spreads for any single NDC can be determined by a review of the range of negotiated reimbursement rates between payors and physicians. He suggests there are two ways that such contracts reveal payor expectations. First, Dr. Hartman notes that the lowest reimbursement rate he identified for PADs was AWP -15% (this apparently means to him

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[56] ASCO Study, p. 37. Emphasis added.

[57] Hartman Deposition at 737:13-19.

[58] See, "Physicians' Costs for Chemotherapy Drugs," Department of Health and Human Services Office of Inspector General, November 1992; and "Excessive Medicare Payments for Prescription Drugs," Department of Health and Human Services Office of Inspector General, December 1997.

that spreads over ASP would be somewhat more that 15%).[59] Dr. Hartman then argues that since payors would intend to leave "some margin" for providers, contract reimbursement rates for the most favorably positioned payors are consistent with his conclusion that expectations for payor spreads could not exceed 30%.[60] He states also that his review of contracts demonstrates that TPPs have negotiated reimbursements for PADs in a range of AWP ± 15%, so that the maximum difference in reimbursement rates between any two payors is 30%.[61] The suggestion appears to be that this 30% variability in reimbursement rates reflects the variability in payor expectations.

72. In Attachment C of his December 2005 Declaration, Dr. Hartman presents only four contracts covering two payors. He says that this is also the range found by the MedPAC report of 2003 which, using data for 2002, showed that TPPs reimburse PADs on average of 97.5% of AWP (*i.e.*, AWP – 2.5%) with the range being 85% to 115%.[62]

73. I note that Dr. Hartman's data on reimbursement rates is limited and his sample does not define the population of contracts that existed throughout the class period. Thus, he cannot conclude statistically that the range of reimbursement rates for any payor did not exceed 30% during the class period. Indeed, statistics indicates that the range of the population of contracts would indeed exceed the range of the sample. Thus, Dr. Hartman should have concluded that the contract reimbursement rates *do not* provide support for the proposition that payor expectations of spreads never exceeded 30%.[63]

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[59] Hartman Declaration, December 15, 2005, FN62, p. 40.

[60] Hartman Rebuttal Declaration, December 16, 2004, p. 63-64.

[61] Hartman Declaration, December 15, 2005, p. 19.

[62] Hartman Declaration, December 15, 2005, pp. 16-17.

[63] With respect to generic drugs, some payors had reimbursement rates below 30%, indicating that they expected that spreads were in excess of 30%. See Hartman Deposition at 759:7-8, for a discussion of Cigna's reimbursement codes that are "up to 45% below AWP." In addition, starting in 2003 Colorado and Connecticut reimbursed generic drugs at AWP-35% and AWP-40% under their Medicaid programs.

74. More fundamentally, Dr. Hartman's theory that the reimbursement contracts "reveal expectations" about spreads for drugs facing therapeutic or generic competition is incorrect.

75. First, the contracts he reports apply a common reimbursement rate to a variety of drugs. Even if one accepted Dr. Hartman's argument that reimbursement rates reveal expectations about spreads, the contractual reimbursement rates would reveal only expectations about *average* spreads and would not inform what was the expected maximum spread for any drug or group of drugs. As a result, the range of discounts in the reimbursement contracts tells us nothing about whether payors expected a 30% limit to the range in the spread for all NDCs and all one year time periods.

76. Although Dr. Hartman does not clearly define what he means by a "market expectation," his analysis of reimbursement rates reveals only his personal expectation and the *minimum* expectation of payors. For example, consider those TPPs paying in the reimbursement range AWP + 15%. For these payors, we clearly know nothing about what they expected, since providers have captured the entire spread (whatever that may be) plus a premium of 15%. According to Dr. Hartman, other providers receive reimbursement rates as low as AWP - 15%, which tells us only that the spread must be *at least* be 15%, but again does not indicate how much higher it might be. Dr. Hartman's use of a 30% yardstick is connected to payor reimbursement contracts only by adding a subjective and arbitrary "some margin" to physicians receiving the 15% minimum observed in the most favorable (to payors) contracts identified by Dr. Hartman.[64] Thus, the yardstick reveals only Dr. Hartman's expectation, not any measure of "market expectations" objectively inferred from the contract data.

77. The problem is compounded by the fact that the reimbursement rates also simultaneously incorporate many other factors, as acknowledged by Dr. Hartman. An expected spread of 100% on ASP (that an ASP that is 50% of the AWP) can just as easily lead to a discount of 15% from an AWP, on average, as an expected spread of 30%. Payors may knowingly

[64] Hartman Deposition at 671:20, 697:13-698:3.

negotiate to permit physicians to retain some portion of the spread larger than the approximate margin assumed by Dr. Hartman. For example, the level of margin that the payors must leave to the providers is determined by their relative market power as well as the optimal composition of the network that payors wish to achieve. Thus, if the provider has significant market power and/or the payor must leave a generous margin to the provider in order to attract the provider to its network, it may agree to a contract reimbursing at a discount of 15% from an AWP even though the payor's expectation was that the physician received an average discount of 50% (or higher) of AWP from the manufacturer. In his rebuttal and damages reports, for example, Dr. Hartman attributes the full 30% range not to differences in expectations about drug spreads, but rather also to differences in relative bargaining power between payors and physicians and other factors:

> Dr. Hartman:
> [S]ome individual payors possess considerable bargaining power and are able to negotiate favorable reimbursement rates at AWP – 15% (*i.e.*, r^{ai}_{f} and r_{f} in Figure 1). Other commercial payors have little bargaining power and can only negotiate least favorable reimbursement rates at AWP + 15% (*i.e.*, r^{ai}_{lf} and r_{lf} in Figure 1). Other payors will fall in between.[65]
>
> ***
>
> . . . some payors will be more successful in bargaining aggressively than others, given their size, strictness of their formularies and the number of lives they insure.[66]
>
> ***
>
> . . . there will be a bell-shaped curve [footnote omitted] summarizing payer reimbursement rates relative to the actual AWP. The position of a given payer on that bell-shaped curve will be determined by its relative size, bargaining strength, information and expectations.[67]

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[65] Hartman Declaration, December 15, 2005, p. 22.

[66] Hartman Declaration, December 16, 2004, p. 59.

[67] Hartman Declaration, December 16, 2004, p. 59.

78. Dr. Hartman has thus failed to test whether the market power of doctors is an "intervening factor" as noted by the Court.[68] This is curious because even in Dr. Hartman's view at least some of the spread income is not due to the alleged fraud but resides in the bargaining position of the physicians:

> Dr. Hartman:
>
> In order to avoid injury, a payor would need full information *and the market power to force all distributors to disgorge the overcharges paid as a result of the AWP scheme*. No single payer existed with that degree of knowledge *and that degree of market power*.[69]
>
> ***
>
> Q: So the desire to have an adequate provider network might be another reason why a payer would not change its reimbursement formula even though it had knowledge of actual ASPs; correct?
>
> A: I'm – I have not done enough of a study to be able to assess or respond to that...the particular monopoly power or the market power on this side of this negotiation in my view would be with the providers as opposed to the payors...."[70]
>
> ***
>
> There's market power by these specialists that provide these kinds of drugs. They are able to negotiate much more aggressively *vis-a-vis* – or refuse to accept certain positions, *vis-a-vis* a payer. They have market power. They are one of the few games in town.[71]

79. Dr. Hartman's revealed expectations theory could be tested empirically. If it is valid, one would expect statistically significant decreases in reimbursement rates over the class period as information about spreads allegedly became more wide spread. In fact, Dr. Hartman does not observe a large drop in reimbursement rates for contracts between payors and physician

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[68] Class Certification Order, p. 74.

[69] Hartman Rebuttal Declaration, December 16, 2004 at FN97, p.62.

[70] Hartman Deposition at 860:4-20.

[71] Hartman Deposition at 1041:8-13, regarding oncologists in upstate New York.

groups over time, which suggests his hypothesis is incorrect.[72,73] He notes that his review of the contract data suggests that contracts were being negotiated at a discount of 15% to 20% from AWP when the contemporaneously available reports suggested much larger spreads of 60% to 80%.[74]

80. Other data also are inconsistent with the theory that reimbursement rates would change in response to information about spreads. For example, plaintiff Blue Cross Blue Shield of Massachusetts's (BCBSMA) Mr. Mulrey testified that BCBSMA estimated it could save millions annually by switching to ASP-based pricing. Despite those savings, BCBSMA has decided to leave its reimbursement rate for PADs unchanged at AWP-5%.[75] Presumably, its expectations about spreads presently are relatively accurate, yet reimbursement rates are unchanged. Mr. Mulrey noted that one consideration could be keeping providers in its network.[76]

81. Faced with data that reimbursement rates have not changed over time in response to new information about spreads, that should have caused him to reject his theory, Dr. Hartman proposes an alternative theory that he fails to test. Dr. Hartman argues that current contracts do not reflect allegedly new information on spreads because of a series of lags: 1) the time required for a relatively small item such as PADs to get on the "radar screen" of something

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[72] Because reimbursement rates differ across payors and physician groups, the relevant comparison is the reimbursement rate for a particular physician group over time, and controlling for other factors that may affect reimbursement rates.

[73] Regarding whether studies showing spreads for single and multi-source drugs informed payor expectations about the relationship between spreads and AWP, Dr. Hartman testified that: "So in answer to your question, there is some information there, but it is, as far as I can see from the contracts and everything else, *this did not affect what – how Medicare was ending up setting its reimbursement rates nor how third-party payer were.*" (Hartman Deposition at 731:17-22) He testified also: "So this kind of information, it was starting to pop up, but this was not shaping general expectations as I see in contracts and in revealed preferences from the sources that I have cited." (Hartman Deposition at 733:4-8)

[74] Hartman Deposition, pp. 197-205 and pp. 218-219.

[75] Deposition of Michael T. Mulrey, January 5, 2006 at 71:22-72:10 & 137:5-11.

[76] Deposition of Michael T. Mulrey, January 5, 2006 at 129:22-130:12.

that needs to be managed; 2) the time required for cumulative evidence of increased spreads to be perceived as a pattern; and 3) the time required for the cumulative evidence to be embodied in contracts that incorporate reimbursement formula that are "hard wired" due to "*status quo* bias."[77]

82. Dr. Hartman's rejection of reimbursement contracts as indicators of changing expectations means that, by his own admission, he has no reliable evidence to confirm his "market expectations yardstick" for liability. In addition, his damage theory is completely divorced from any reliable and contemporaneous evidence on expectations, and we are left only with Dr. Hartman's assertion that his theories will be supported by changing reimbursement rates at some future time.[78]

E. Economic Logic

83. Dr. Hartman's theory that payors would not expect spreads to increase as competition for a new drug enters is not plausible as a matter of economic logic. AWPs clearly are visible to payors through claims data and published sources. For example, suppose payors observe that the AWP for a single-source innovator drug remains the same or increases over time. Over that same period, payors also can observe that therapeutic competitors enter and later that generic competitors enter. Dr. Hartman's assumption requires that payors did not expect that selling prices would drop in the face of such new competition and that, indeed, if the AWP increased over time, the selling price must have increased correspondingly. He provides no evidence that payors lacked the simple intuition that prices would decline once a monopoly provider faced competition, as would be expected in virtually any market. Indeed, Dr. Hartman himself argues and cites evidence that it was widely understood that

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[77] Hartman Deposition at 840:19, 932:20-933:2, 936:10-937:5, 945:1-20, 947:15-948:3, 956:10-18, 957:14-959:3, 972:15-973:3, 973:12-974:20, 977:4-979:10, 1003:2-12. Professor Meredith Rosenthal, another witness for the class, agrees. At her deposition at 104:15-22, she says: "There's a feasibility concern ... it's very arduous to change claims systems to adapt to a new set of information."

[78] Hartman Deposition at 958:15-17: "That doesn't mean that they're not going to reveal their preferences a year from now ...."

ASPs for self-administered drugs fell dramatically as generic competition entered the market:

> Dr. Hartman:
>
> [O]nce a generic launches, its AWP usually remains constant (or may increase slightly), *while the ASP of the drug is known to decline precipitously with multiple generic launches over time, relative to the pre-generic-launch branded price and, by implication, relative to the generic AWP...[T]his pattern for generic prices is well known* and has been well-documented in the scientific peer-reviewed literature...[79]
>
> ***
>
> For generic drugs, once generic manufacturers announce their AWP (the first generic manufacturer with 180-day exclusivity always announces first), the generic manufacturers compete on ASP in order to move market share. The prices (ASPs) of generic drugs follow *a predictable trajectory* from the pre-generic launch brand-name price (and from the generic AWP) toward variable production cost as more generics come into the market; see the many analyses in footnote 62.[80]

84. Dr. Hartman, however, states that this widely understood expectation applied only to self-administered drugs because physician administered multi-source drugs were "less scrutinized or understood."[81] Even if true, the lack of information does not compel or even support the conclusion that payors expected their spreads to be the same as monopoly drugs and relied on that expectation in their negotiations.

85. It is also curious that Dr. Hartman ignores the fact of higher spreads even for generic and self-administered drugs at issue in this case. For example, I understand that Albuterol manufactured by Warrick, a drug for which Dr. Hartman finds liability and damages using his yardstick, was generic and primarily self-administered.[82]

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[79] Hartman Rebuttal Declaration, December 16, 2004, p. 39.

[80] Hartman Rebuttal Declaration, December 16, 2004, FN95, pp. 66-67.

[81] Hartman Deposition at 965:8-966:7.

[82] Declaration of Harvey J. Weintraub.

86. Instead of testing the critical hypothesized relationship between expectations and reimbursement rates, Dr. Hartman simply assumes his conclusion that reimbursement rates would change with changes in expectations when he rejects direct evidence about expectations as unreliable unless it leads to changes in reimbursement rates:[83]

> Dr. Hartman:
>
> When I see (payors) start to say, look, we want to reimburse on acquisition cost and there is a definition of what that means, that will say to me that they...are now revealing an understanding of the fact that these spreads are well above what the – what we thought they were.[84]

87. In summary, Dr. Hartman offers no evidence that the class members had expectations about spreads that informed their reimbursement rates, and if they did, no evidence of what any expectations were. He does not offer any evidence that whatever expectations of spreads

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[83] See also Hartman Deposition at 823:6-16: "As a matter for an economist, one finds that preferences and expectations are revealed when behavior is exhibited, and when there is a shift in the way reimbursement is paid or contractually the way -- what kinds of discounts are offered off of AWP or whether it is related to ASP. That then shows that there has been enough information that they have come to an understanding that is sufficient to make them move to avoid the problems that are slowly becoming clear to them."

Dr. Hartman testifies about the fact that BCBSMA, a class representative in this case, continues to reimburse PADs at 95% of AWP: "[T]his doesn't contradict anything that has been put forward here. They have yet to reveal how they are going to respond when they commit to changing the - a system that has been put in place based on older expectations that have since been violated." (Hartman Deposition at 841:11-15)

Dr. Hartman explained that: "[W]hen third-party payors say we're reimbursing on ASP or AWP less 70 percent, that will reveal to me that enough of this information has been reflected in – in their behavior." (Hartman Deposition at 985:8-11).

Similarly, Dr. Hartman testified: "Q: Evidence that (spread competition for multi-source PADs) was common knowledge would be of interest to you, correct? A: Evidence that reimbursements should change as a result of the fact that -- that the – the patterns that have been put in place should be altered to eliminate the amounts of money that were being made, that should be changed, that would be of interest to me." (Hartman Deposition at 1003:13-20).

[84] Hartman Deposition at 788:17-789:1.

that may have existed fell into a relatively narrow range that never exceeds 30%.[85] Because AWPs are transparent to payors and competition was known and would be expected to reduce ASPs, it would be reasonable as a matter of economic logic to expect that spreads for drugs facing competition exceeded those for single-source innovator drugs.[86] Indeed, to the extent that the data and documents used by Dr. Hartman to estimate his yardsticks reflected or informed payor expectations, they indicate that payors would expect that spreads for drugs facing therapeutic or generic competition would exceed spreads for drugs that did not face such competition.[87]

VI. DR. HARTMAN'S DAMAGES ANALYSIS: WHAT WOULD AWP, ASP, AND REIMBURSEMENT RATES BE IN THE ABSENCE OF THE ALLEGED FRAUD?

88. Recall that the fundamental premise of Dr. Hartman's liability analysis is that pharmaceutical companies increased spreads to increase sales volumes and that payors were ignorant of these spreads. Dr. Hartman articulated the view that had payors known about the spreads, they would have adjusted reimbursement rates in response to capture for themselves the discounts from list price offered to physicians exceeding the 30% "yardstick."[88]

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[85] Indeed, Dr. Hartman testified that "I cannot make the statement that no one, no payer, knew that there weren't mega-spreads. I, you know, I don't know whether they did or they didn't." (Hartman Deposition at 796:6-10).

[86] Plaintiffs' expert Dr. Rosenthal has acknowledged that therapeutic competition would be expected to result in discounting and increased spreads. For example, she testified: "I do think the amount of therapeutic competition in terms of the effects of the drugs and side effects would be a factor in that kind of discounting." (Rosenthal Deposition, February 22, 2006 at 87:11-14).

[87] The finding in the studies cited by Dr. Hartman that spreads did in fact exceed 30% for some drugs was also reflected in a 1996 *Barron's* article that stated that "For many drugs, especially the growing number coming off patent and going generic, the drug providers actually pay wholesale prices that are 60-90% below the so-called average wholesale price..." A discount of 90% results is a spread of 1000%. A table accompanying the articles showed drugs with even higher spreads. See Alpert, B., "Hooked on Drugs," *Barron's*, June 1996, pp. 15-18.

[88] For example, Hartman Declaration, December 15, 2005, pp. 9-10.

89. It might be expected that to determine his but-for world, Dr. Hartman would estimate what reimbursement rates would have been for each payor had they known the increased spreads. Dr. Hartman makes no such analysis. Instead, his model assumes that reimbursement rates outside of Medicare and selling prices to physicians would be unchanged. He assumes that the pharmaceutical companies would have changed their reported AWP in order to maintain the same relationship to ASP for drugs that faced therapeutic or generic competition as for those that did not. For Medicare damages, Dr. Hartman applies a different but-for AWP than for non-Medicare claims, which is of course impossible. But he appears to do so as a computational short-hand to implement his legal interpretation of reimbursement required by statue.

A. Non-Medicare Payors

90. Dr. Hartman applies one formula to calculate damages for all class members, all drug categories, and at all times during the damage period for non-Medicare claims. Damages are based on the product of the reimbursement rate and the calculated gap between the actual AWP and the but-for AWP, (*i.e.*, the AWP that would have been observed but for the alleged fraud):

(1) Damages for non-Medicare = contract reimbursement rate * (As-is Spread – But-for Spread) * ASP * Quantity

91. Note that the *only* variable that is different between the but-for and the as-is worlds in Dr. Hartman's damages formula is the AWP – all other variables retain the same values. The but-for AWPs for each NDC are estimated by reference to actual ASPs and incorporate the maximum spread that Dr. Hartman assumes payors would expect across all drugs (30%).[89] The reimbursement rate, *which is the mechanism by which Dr. Hartman argued payors*

[89] Although Dr. Hartman testified that the relevant ASP was the ASP paid by physician-providers, his supplemental report calculates a lower ASP (thereby increasing damages) based on all transactions, including for example more heavily discounted sales to hospitals. (See, for example, Hartman Deposition at 658:11-661:13).

would adjust to information about spreads (and therefore the variable that would change in the but-for world), is unchanged.[90]

92. There are two alternative interpretations of Dr. Hartman's approach to damages. The first and most direct is that he indeed expects that absent the fraud, pharmaceutical companies would have adjusted their AWPs downward as he assumes and all other variables would remain unchanged. I show that this result simply will not occur if the drug companies are free to set spreads as competitive conditions warrant and can cure the alleged fraud by correcting plaintiffs' allegedly misinformed expectations. This is because pharmaceutical companies will face the same basic economic incentives to increase spreads to compete regardless of whether payors are informed about the spreads.

93. The only way that Dr. Hartman's but-for spreads would exist for drugs facing competition is if they were mandated legally. In that scenario, liability for fraud and damages now arises *per se* from price competition to "move market share," irrespective of plaintiff expectations in the real world -- there is no longer any causal link between expectations and the alleged fraud. Even under that scenario, Dr. Hartman's conclusions are incorrect. AWP and ASP will not drop as Dr. Hartman predicts in the face of new competition, and indeed AWP and ASP would likely be *higher* as a result of the incentives that would face drug companies and physicians if spreads were constrained legally not to exceed 30%.

94. Finally, I consider and dismiss the possibility that Dr. Hartman's model might correctly estimate the quantum of damages that would arise not through changes in but-for AWP, but

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[90] Recall that a critical assumption of Dr. Hartman's liability theory is that reimbursement rates would be different in the but-for world where payors know of the alleged inflated spreads. See Hartman Declaration, December 15, 2005, pp. 9-10:

> Dr. Hartman
> The negotiation also relies upon an anticipation that the AWP provides a signal for the underlying spreads. Had the existence of the "mega-spreads" been perceived and understood by TPPs, those payers would have negotiated more aggressively than they did, leading to lower reimbursement rates. (Footnote omitted)

through changes in reimbursement rates. In this alternative, Dr. Hartman would not mean his formulaic approach to be interpreted as written. Rather he would believe that reimbursement rates would in fact adjust to capture fully the difference between the as-is and the but-for spreads. That is, his formula is a simpler way of estimating the quantum of damages rather than reflecting also what the fraud-free world looks like. I show that this too is incorrect.

1. Would AWP Drop and ASP Remain Unchanged as Dr. Hartman Predicts if Payors Were Informed?

95. Dr. Hartman's model appears to assume that fraud is defined as spreads that were unknown to payors, but companies are free otherwise to set their prices and to compete. Then it is necessary to ask whether competition would drive drug companies in the fraud-free world to keep ASPs at the same levels as they did in the as-is world. If so, we must also ask whether it would drive them also to have dropped AWPs to maintain a spread of not more than 30%.

96. To begin, note that if the fraud is defined in terms of expectations, then it can be cured by informing the expectations rather than by conforming spreads to some defined limit. For example, drug companies could announce that published AWP bears no "reasonably predictable" relationship to ASP.[91] If required, drug companies might publish more information about specific spreads. Even in this case, however, increasing spreads to physicians would remain an effective way for drug manufacturers to compete in the Hartman damage methodology.

97. The intuition is straightforward. If the alleged fraud is cured by changing alleged payor expectations, drug companies would continue to compete by increasing spreads to gain market share as competition increases.

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[91] At least one manufacturer, Schering Corporation, has provided such a disclosure. See SP Ex. 40 (WAR 0065610), an April 2003 price list provided to the Connecticut Commission that states "[t]he AWP shown is not an average of wholesale prices, nor does it reflect the price of any wholesale transaction."

98. The incentive to change spreads to attract volume does not arise from the alleged hidden nature of the spreads from the point of view of payors. It arises because cutting price and increasing spreads make drugs more attractive economically to the physicians that prescribe them.[92] Thus even if payors knew that there was no predictable relationship between AWP and ASP for all drugs, and even if spreads or ASPs were published, competition for sales to physicians would continue to create pressure to increase spreads. This is in fact the normal competitive process of firms cutting prices in response to competition in order to gain a temporary market share advantage.[93]

99. It should be clear, therefore, that the but-for world in Dr. Hartman's model, where reimbursement rates and ASPs and reimbursement rates do not change but AWP drops to keep spreads under 30, cannot be taken literally as he presents it. If fraud depends on expectations, the expected competitive result would be to provide whatever minimum information cures the fraud, rather than to cut AWP so that spreads are no more for drugs facing competition than they are for drugs that do not. That is, even in the fraud-free world, pharmaceutical companies will continue to face competitive pressure to increase spreads. Dr. Hartman's analysis therefore requires that fraud is independent of expectations. That is, the definition of fraud presented in his initial report and reiterated in his damage report must now be changed to a *per se* theory to support his damage calculations. Alternatively, to be consistent with his liability theory, he must argue that AWP would not drop as his formula asserts, but rather that reimbursement rates would adjust so that an economically equivalent result is obtained by payors.

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[92] In some cases, spreads may be increased by raising AWP. However, this would not be secret, as explained above. I note that raising the list price while providing discounts to some customers would be expected where there exists a price-insensitive segment of customers paying list prices and a more price sensitive segment that negotiates for discounts.

[93] Note that even informed expectations are not instantaneously informed, so that there remains an incentive to cut price to increase volume even if the prices subsequently become public. I discuss below why instantaneous information generally undermines the normal competitive process by eliminating the motivation for the supplier to cut prices in the first place.

2. *Would AWP Drop as Dr. Hartman Predicts and ASP Remain Unchanged if Drug Companies Were Confined to a Regulated Spread?*

100. Above I showed that the only way for Dr. Hartman's damage formula to hold as it is presented (see equation (1) above) would be to define spreads above a certain level as *per se* illegal. In this case there would be no causal connection between 1) Dr. Hartman's damages calculations and 2) any alleged discrepancy between actual and expected spreads.[94] Fraud would arise not because spreads were higher than payors expected, but rather simply because spreads exceed 30%, regardless of what spread payors expected.[95]

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[94] This offering of an entirely different causal connection between liability theory and damages that is divorced entirely from expectations in the actual world is clear when:

i. Dr. Hartman argues that even though some plaintiffs may have had no expectations of spread in the real world and did not rely on them to negotiate contracts, they must nevertheless have been harmed by fraud: "*Even if a Class member did not care about the relevant distributor's acquisition costs, that Class member was still injured and overcharged by the extent to which the AWP was artificially inflated above the but-for AWP*, since the reimbursement rates paid by that class member were formulaically referenced to those AWPs and were therefore subject to an overcharge." (Hartman Deposition, December 16, 2004, p. 21. Emphasis added).

This result occurs in fact in the damage model because it calculates damages regardless of expectations based on the "spread gap" created by assuming that there is no generic or therapeutic competition in the but-for world;

ii. He argues that "comparator drugs" used to calculate but-for spreads should be those not facing generic or therapeutic competition, because "a given manufacturer would find it unnecessary and unprofitable to increase spreads to move market share" if it were not for competition (Hartman Declaration, December 15, 2005, pp. 15-16. Emphasis in original);

iii. He claims that evidence of spreads greater than 30 percent support the conclusion that ". . . the manufacturer has fraudulently increased the spread on that NDC in that period to move market share" (Hartman Declaration December 15, 2005, p. 40); and

iv. He cites the report of Professor Rosenthal on liability, who concludes that "I concluded in my report that the class was harmed because these incentives [of manufacturers to compete with spread] were present." See Rosenthal Deposition at 377:19-20.

[95] See Hartman Deposition at 938:2-5:

Q. So, the basis for any opinion on liability you may give is simply a comparison of actual spreads with yardstick spreads, correct?
A. That's correct.

101. This *per se* description of fraud is in fact the only logical way to interpret the yardsticks selected by Dr. Hartman. Specifically, the yardsticks attempt to identify what spreads would be absent competition rather than what expectations of the class members actually were in the as-is world and how they affected reimbursement rates. Damages now arise whenever defendants act to "move market share," irrespective of payor expectations or contracting behavior:

> Dr. Hartman:
>
> Specifically, if a manufacturer either raises its AWP and/or lowers its ASP such that the realized spread exceeds 30% for a given NDC for a given period of time (I choose a year), I conclude that the manufacturer has fraudulently increased the spread on that NDC in that period to move market share.[96]

102. Note that in describing fraud as he applies it in his liability and damages model, Dr. Hartman now uses the concept of "expectations" to refer not to the actual expectations of the class members, but rather to what expectations would be if drug companies never competed by increasing spreads and spreads were kept at levels consistent with those for drugs not facing competition.[97]

> Dr. Hartman:
>
> [S]uccessful 'break-through' innovator drugs serve as reasonable yardsticks for 'but-for' spreads, specifically, for spreads that would be anticipated in the market *in which spread manipulation was*

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[96] Hartman Declaration, December 15, 2005, p. 40.

[97] This definition of expectations explains why despite the fact that Dr. Hartman claimed in his rebuttal report that the fact that spreads for self-administered generic drugs were "well known and has been well-documented," he claims in his later report that "[t]here is no evidence that the yardsticks for TPP price expectations for multi-source physician-administered drugs were any different than those for single-source physician-administered drugs....As a result, I use the same yardstick for liability for all physician-administered drugs, whether single-source or multi-source." (Hartman Declaration, December 15, 2005, p.42). He cannot mean actual expectations in the as-is world but rather expectations of what spreads would be if companies could not use them to compete.

> *unnecessary to move market share* for single-source branded drugs reimbursed by Sub-Class 3.[98]

103. If this definition of fraud is accepted, the relevant question now becomes whether ASPs would drop to the levels actually observed in the world where competition based on spreads took place if drug companies were legally required by a *per se* rule to limit spreads to no more than 30%. The answer clearly is "no."

104. It should give immediate pause to consider that in this scenario, Dr. Hartman's damages calculation would require that companies that cut prices in order to increase volume ("to move market share") would nevertheless cut them to the same extent *even when price cuts would create no such incentive because spreads would be unchanged.*[99] As Dr. Hartman explained, " ... the only reason that you would lower your – the – your unit revenue, your average sale price would be to take advantage of being able to move market share."[100]

105. If spreads beyond the initial level set for single-source innovator drugs are deemed to be *per se* illegal, how would competition occur for physician-administered drugs where formulary control is not feasible?[101] Since volume cannot be changed by increasing spreads, what is the incentive to cut price as competition enters? There is none: regulation of spreads by defining price cutting "to move market share" as *per se* fraudulent if spreads exceed 30% in

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98 Hartman Declaration, December 15, 2005, p. 16. Emphasis added.

99 Cuts in ASPs that would otherwise cause spreads to exceed 30% would require an offsetting reduction in AWPs, thereby undercutting the incentive effect of the price cut on providers and the profit motive to drug manufacturers.

100 Hartman Deposition at 1144:1-4.

101 For example, Dr. Hartman argues that "[C]ritical review of a provider's choice of drug therapy and the price of the selected drug is most typically believed to be beyond the expertise of the TPP. The provider determines the drug being administered. The choice of drug is determined by the training of the provider and the provider's specific knowledge of the patient, the patient's clinical profile and the patient's medical needs. (Hartman Declaration, December 15, 2005, p. 41); and that "[n]ot only do TPPs feel medically inadequate to review physician/provider choice of therapy, TPPs correctly believe that such review is not cost-effective." (Hartman Declaration, December 15, 2005, p. 41).